## 6. 510(k) Summary

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|---|---|
| **Manufacturer:** | U & I Corporation<br>20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859 |
| **Sponsor:** | U & I Corporation<br>20, Sandan-ro 76beon-gil(Rd), Uijeongbu-si, Gyeonggi-do, Korea, 480-859 |
| **Sponsor Contact:** | Young-Geun Kim, Regulatory Affairs Assistant<br>+82 31 852 0102 (ext.619)<br>ygkim@youic.com |
| **Date Prepared:** | February 18, 2014 |
| **Device Name:** | Trade Name: ASPIRON™ ACP System |
| **Submission Purpose:** | To expand the ASPIRON™ ACP System to include shorter plate sizes and introduce new types of bone screw |
| **Classification Name:** | Spinal Intervertebral Body Fixation Orthosis, per 21 CFR 888.3060 |
| **Common Name:** | Anterior Cervical Plate |
| **Product Code:** | KWQ |
| **Predicate Devices:** | Maxima™ Anterior Cervical Plate System (K061002)<br>Blackstone™ III° Anterior Cervical Plating System (K012184)<br>ZEPHIR™ Anterior Cervical Plate System (K994239)<br>Venture™ Anterior Cervical Plate System(K061274)<br>INDUS™ INVUE Anterior Cervical Plate System(K121060)<br>ASPIRON™ ACP System (K131200) |

**Description of Device:**

The ASPIRON™ ACP System consists of a variety of shapes and sizes of bone plates, screws and associated instruments. Fixation is provided by bone screws inserted into the vertebral body of the cervical spine using an anterior approach. All implant components are made from titanium alloy (Ti-6Al-4V ELI) in accordance with ASTM F136. The main plate and screws are anodized according to the internal process (5% Phospheric acid solution under pH 1.5). The same anodizing process is also applied to the conventional ASPIRON™ ACP System(K131200) and

Maxima(K061002). This material is not compatible with other metal alloys. Stainless steel and titanium implant components should not be used together in a construct. Do not use any of the ASPIRON™ ACP System components with the components from any other system or manufacturer. All implants are single use only. The Type 2 of screws and short plates are added to the conventional ASPIRON™ ACP System in this submission. Type 2 screw has thread until the tip of screw for easy insertion.

**Intended Use:**

The ASPIRON™ ACP System is intended for anterior inter-vertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative disc disease (as defined by neck pain of discogenic origin with degeneration disc confirmed by patient history and radiographic studies);
- Spondylolisthesis
- Trauma (including fractures, dislocation)
- Spinal stenosis
- Tumors
- Deformity (defined as scoliosis, kyphosis, or lordosis)
- Pseudoarthrosis
- Failed previous fusion

WARNING: The device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic or lumbar spine.

**Substantial Equivalence:**

The ASPIRON™ ACP System is substantially equivalent to predicate legally marketed devices in design, material, mechanical performance, function and intended use. The mechanical performance of ASPIRON™ ACP System met the acceptance criteria which have been established from the predicate devices.

1. Comparison Technological Characteristics

The predicate and proposed devices have the similar intended use and basic fundamental scientific technology and share the following similarities;

- The similar indications for use
- Similar design features
- Incorporate the same or similar materials
- The equivalent mechanical performance

2. Performance Testing

The ASPIRON™ ACP System was tested in a non clinical setting (bench testing) to assess that to no new safety and efficiency issues were raised with this device. The testing met all acceptance criteria and verifies that performance of the ASPIRON™ ACP System is substantially equivalent to the predicate devices. The compression bending fatigue test was performed according to ASTM F1717.

3. Conclusion

The data and information provided in this submission support the conclusion that the ASPIRON™ ACP System is substantially equivalent to its predicate devices with respect to indications for use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 2, 2014

U & I Corporation
Mr. Young-Geun Kim
Regulatory Affairs Assistant
20, Sandan-ro, 76beon-gil (Rd)
Uijeongbu-si, Gyeonggi-do
Republic of Korea 480-859

Re: K140234
Trade/Device Name: ASPIRON™ ACP System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: April 30, 2014
Received: May 5, 2014

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Ronald P. Jean -S for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

## Indications for Use Statement

**510(k) Number (if known):** K140234

**Device Name:** ASPIRON™ ACP System

### Indications for Use:

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Prescription Use —X— (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ——— (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE, CDRH)

Anton E. Dmitriev, PhD

Division of Orthopedic Devices

U&I CORPORATION